UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

United States of America, and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia, and the Cities of Chicago and New York, Plaintiffs, *ex rel.* SHAWN BATES, EDWARD JOSEFOSKI and ROBERTA LESSER Relators, v. DENTSPLY INTERNATIONAL, INC., ASTRAZENENCA, and ASTRA TECH (n/k/a WELLSPECT) Defendants.	Civil Action No. 12-CV-7199 **FILED UNDER SEAL** **Pursuant to 31 U.S.C. §3730(b)(2)** JURY TRIAL DEMANDED FILED JAN - 9 2014 MICHAEL E. KUNZ, Clerk By _____ Dep. Clerk

AMENDED FALSE CLAIMS ACT COMPLAINT

I. INTRODUCTION

1. This action, brought by Relators Shawn Bates, Edward Josefoski and Roberta Lesser (collectively, "Relators"), is to recover damages and civil penalties on behalf of the United States of America, and state and local governments arising out of false claims and records presented by Defendants DENTSPLY International, Inc. ("DENTSPLY"), AstraZeneca, and Astra Tech AB to the United States and to the States of California, Colorado, Connecticut, Delaware, Florida,

Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, as well as the District of Columbia, and the Cities of Chicago and New York ("*Qui Tam* States").

2. This action arises under the provisions of Title 31 U.S.C. § 3729 *et seq*., known as the False Claims Act ("FCA"), and pursuant to analogous provisions of state and local law, including, but not limited to the following:

California False Claims Act, Cal. Gov't Code § 12651 *et seq*.
Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq*.
Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq*.
Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201 *et seq*.
Florida False Claims Act, Fla. Stat. § 68-081 *et seq*.
Georgia False Medicaid Claims Act, Ga. Code § 49-4-168 (2007)
Hawaii False Claims Act - False Claims to the State, Haw. Rev. Stat. § 661-21 *et seq*.
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 *et seq*.
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq*.
Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.1 *et seq*.
Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-601 *et seq*.
Massachusetts False Claims Act, Mass Laws Ch. 12, § 5(A) *et seq*.
Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq*.
Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*.
Montana False Claims Act, Mont. Code § 17-8-401 *et seq*.
Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.010 *et seq*.
New Hampshire Medicaid False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq*.
New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.
New Mexico Medicaid False Claims Act., N.M. Stat § 27-14-1 *et seq*.
New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq*.
North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.
Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq*.
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*.
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq*.
Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-181 *et seq*.
Texas Medicaid Fraud Prevention, Tex. Hum. Res. Code § 36.001 *et seq*.
Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq*.
Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq*.
District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq*.
City of Chicago False Claims Act, Mun. Code, § 1-22-010 *et seq*.
New York City False Claims Act, Adm. Code § 7-801 *et seq*.

(collectively, "State *qui tam* statutes").

3. This case is brought pursuant to the *qui tam* provisions of the FCA and pursuant to analogous provisions of state and local law (cited above), to recover treble damages and civil penalties on behalf of the United States of America and the *Qui Tam* States, arising from false or fraudulent claims for reimbursements for medical devices and other products that were submitted or caused to be submitted by Defendants to federal government-funded programs including, without limitation, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration in violation of the FCA. The FCA specifically proscribes Defendants' conduct involving unlawful marketing of medical devices and illegal kickbacks, and thus the submission of false or non-reimbursable claims to Medicare, Medicaid and other government-funded health programs.

4. The suit involves violations by the Defendants relating to the marketing and promotion of dental medical devices and products.

5. Relators Bates and Josefoski are former employees of DENTSPLY's Implants Sales Division.

6. Relator Lesser is a current employee of DENTSPLY's Implants Sales Division.

7. DENTSPLY claims it is the world's largest designer, developer, manufacturer and marketer of a broad range of professional dental products, including dental consumable products, dental laboratory products and dental specialty products.

8. During 2011, DENTSPLY purchased Astra Tech AB from AstraZeneca, which greatly expanded DENTSPLY's dental specialty products and increased certain medical device product lines.

9. Defendants' prohibited and other illegal marketing activities in violation of the FCA, the State *qui tam* statutes and United States Food and Drug Administration ("FDA") laws and regulations include, but are not limited to:

a. Misrepresenting and downplaying the adverse effects of various DENTSPLY products;

b. Illegally marketing various DENTSPLY products to dental healthcare professionals, including dentists, oral surgeons, periodontists, prosthodontists, endodontists, and/or orthodontists for the treatment of medical issues and/or in populations for which is the DENTSPLY products were not approved;

c. Establishing "Return on Investment" ("ROI") initiatives in the form of paid speaker programs and product sampling;

d. Violating "best price" practices in relation to various DENTSPLY products; and

e. Using company and personal funds for dinners and other activities to induce dental healthcare professionals to use additional various DENTSPLY products.

10. Defendants' FCA violations and their various marketing schemes corrupted the independent medical judgment of dental healthcare professionals and/or other healthcare professionals, unlawfully increased costs to the United States and the *Qui Tam* States for medical devices, and risked patients' health by improperly influencing physicians' decisions about whether to prescribe or use DENTSPLY and/or Astra Tech products.

11. Defendants knew or should have known that their unlawful activities would cause dental healthcare professionals and/or other healthcare professionals to routinely file false claims for reimbursement from the Federal and State governments in violation of the FCA and state and local law, and involved violations of the Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq.*, the Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 *et seq.* and 21 U.S.C. § 360aaa *et seq.*, the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a *et seq.*, the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, and similar State laws.

12. Defendants' schemes illegally increased the federally-funded and state-funded market share for various DENTSPLY and Astra Tech products by inducing dental healthcare professionals to prescribe or utilize products they would not otherwise have prescribed or used, but for the receipt of kickbacks, misinformation, and other illegal marketing efforts. Federal and state governments consequently paid enormous sums for reimbursement claims they would have otherwise rejected had each been aware of Defendants' illegal actions. Moreover, as a result of Defendants' illegal promotions, the public over-utilized Defendants' devices and products so that costs to the Federal and State governments soared, while Defendants increased their profits substantially.

13. Defendants chose to promote their products and devices for off-label uses, despite Defendants' awareness of the FDA's prohibition of off-label marketing.

14. Defendants also promoted their products and devices for uses not FDA-approved, resulting in substantial fraud on the federal and state governments.

15. Defendants also paid kickbacks to various dental healthcare professionals and violated "best price" practices to the detriment of patients' health and causing substantial financial harm to government-funded health care programs.

16. Defendants' off-label and other illegal marketing practices resulted in substantial loss to the federal and state governments.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the State False Claims Acts pursuant to 31 U.S.C. §

3732(b), as well as supplemental jurisdiction over the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 1367.

18. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this district.

19. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c). All Defendants transact business within this District and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

20. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint is filed under seal and will remain under seal for a period of 60 days or more from its filing date or such other date as the Court so orders, and shall not be served upon the Defendants unless the Court so orders.

21. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A), amended by Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relators have, however, affirmatively disclosed the allegations herein to the United States FDA, the *Qui Tam* States, and the United States Department of Justice, including prior to filing this case and/or amendments to the Complaint.

22. Relators have direct and independent knowledge on which the allegations are based, are original sources of this information to the United States and the *Qui Tam* States, and have

voluntarily provided the information to the United States before filing this action based on the information.

23. To the extent that there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relators, Relators are an original source of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010) and similar state law provisions.

24. Relators possess direct and independent knowledge of the information as a result of an extensive independent investigation they personally conducted into Defendants' wrongdoing, which they acquired in the course of their employment with Defendants and thereafter, as a result of their investigation.

25. Relators voluntarily provided the government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

III. THE PARTIES

26. Relator Shawn W. Bates ("Relator Bates") was employed by DENTSPLY International, Inc. in its Implant Sales Division as a Senior Regional Sales Manager in Virginia until May 2012, and was hired into the DENTSPLY Tulsa Dental division in January 2010. Relator Bates has worked in the healthcare industry since May 2001, either in a sales or managerial capacity. Relator Bates holds a Bachelor of Arts degree from The Citadel, South Carolina. Relator Bates is a former U.S. Army officer. Relator Bates has been the recipient of various awards throughout his professional career, including at DENTSPLY.

27. Relator Edward Josefoski ("Relator Josefoski") was employed by DENTSPLY International, Inc. in its Implant Sales Division as a District Sales Manager in Pennsylvania until August 2013, and was hired into the DENTSPLY Tulsa Dental division in 2010. Relator

Josefoski is a citizen of the Commonwealth of Pennsylvania. Relator Josefoski has worked in the healthcare/medical device industry since 2000. Relator Josefoski has been the recipient of various awards throughout his professional career.

28. Relator Roberta Lesser ("Relator Lesser") is employed by DENTSPLY International, Inc. in its Implant Sales Division as a District Sales Manager in Massachusetts, and was hired into the DENTSPLY Tulsa Dental division in August 2006. Relator Lesser has previously served as, among other positions, a Regional Business Development Specialist – Implants and Biologics and Senior Territory Manager for the DENTSPLY Tulsa Dental division. Relator Lesser has been the recipient of various awards throughout her professional career, including at DENTSPLY.

29. Defendant DENTSPLY International, Inc. ("DENTSPLY") is a Delaware corporation doing business throughout the United States. DENTSPLY's corporate headquarters and principal place of business is located at 221 West Philadelphia Street, York, Pennsylvania. Upon information and belief, DENTSPLY's net sales exceeded $2.5 billion in the year 2011.

30. DENTSPLY's products comprise three general groups: dental consumables; dental laboratory products; and dental specialty products.

31. At all times pertinent to the averments of this Complaint, DENTSPLY was engaged in the business of developing, manufacturing, marketing, and selling various laboratory and specialty products relating to dental supplies.

32. At all times pertinent to the averments of this Complaint, DENTSPLY, with regards to consumable products, was engaged in the business of developing, manufacturing, marketing, and selling anesthetics, plaque and gum disease prevention and tooth polishers. DENTSPLY also designs and constructs artificial teeth.

33. DENTSPLY has a number of divisions. Many divisions are regional in terms of their base and the market they serve (i.e., in Asia are named after the country they serve), while others are focused on a specific product (*i.e.*, DENTSPLY Ceramco deals in prosthetics, DENTSPLY Maillefer deals in endodontics). The divisions and subsidiaries sell their products through regionally focused distribution companies as well as dental healthcare professionals and dental schools.

34. The divisions at issue here are:

a) DENTSPLY Federal Government;

b) DENTSPLY Caulk (restoratives/impression materials);

c) DENTSPLY Ceramco (crown and bridge);

d) DENTSPLY GAC (orthodontics);

e) DENTSPLY Maillefer (endodontics);

f) DENTSPLY Implants (implants, regenerative, CAD/CAM abutments, guided surgery);

g) DENTSPLY Pharmaceutical (anesthetics);

h) DENTSPLY Professional (Preventive & Midwest) (preventive, handpiece & burs);

i) DENTSPLY Raintree Essix (orthodontics, plastics);

j) DENTSPLY Rinn (x-ray accessories/Crescent);

k) DENTSPLY Tulsa (endodontics);

l) DENTSPLY Friadent CeraMed (implants and grafting); and

m) DENTSPLY Trubyte/Austenal (removable full dentures).

35. All of these divisions should be considered defendants in this action, but are controlled and managed by DENTSPLY International, Inc.

36. DENTSPLY distributes approximately 56% of its dental products through distributors and importers. However, certain highly technical products such as precious metal dental alloys, dental ceramics, crown and bridge porcelain products, endodontic instruments and materials, orthodontic appliances, implants, and bone substitute and grafting materials are sold directly to the dental laboratory or dental professionals in some markets. During 2009, 2010 and 2011, one customer, Henry Schein Incorporated, a dental distributor, accounted for 11% of DENTSPLY's consolidated net sales in each year. No other single customer represented ten percent or more of DENTSPLY's consolidated net sales during 2011, 2010 or 2009.

37. The primary distributors and/or importers are:

a) Henry Schein, Inc.;

b) Benco Dental Supply;

c) Patterson Dental Co.;

d) Ultimate Dental;

e) Tri-State Dental Supplies;

f) Smart Practice;

g) Pearson Dental Supply Co.;

h) Orange County;

i) Newark Dental Corporation;

j) Nashville Dental Inc.;

k) Midwest Dental Equipment and Supply;

l) Iowa Dental Supply Co.;

m) Holt Dental Supply Inc.;

n) Goetze Dental Co.;

o) Direct Dental Supply;

p) Dental Health Products, Inc.;

q) Darby Dental Supply, LLC;

r) Burkhart Dental Supply;

s) Atlanta Dental Supply Co.; and

t) Arnold Dental Supply Company.

38. In August 2011, DENTSPLY purchased Astra Tech AB, AstraZeneca's dental implants and medical devices unit, for $1.8 billion.

39. Defendant AstraZeneca is incorporated in the state of Delaware. Its headquarters and principal place of business are in Wilmington, Delaware. AstraZeneca is a global research-based biopharmaceutical company involved in the development and marketing of prescription medicines and medical devices. In the twelve months ending on September 10, 2010, AstraZeneca has generated net revenue in excess of $33 billion.

40. AstraZeneca has previously been punished for violating the False Claims Act. Most recently, AstraZeneca was fined $520 million to resolve allegations that it marketed the anti-psychotic drug Seroquel for off-label uses. The fine arose from *qui tam* actions that included allegations that AstraZeneca promoted Seroquel to doctors who do not typically treat schizophrenia or bipolar disorder, for which the drug is FDA approved. Instead, Seroquel was marketed to physicians who treat the elderly, primary care physicians, pediatric and adolescent physicians, and in long-term care facilities and prisons for the treatment of unapproved uses

including Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder and depression.

41. As a result of the settlement involving Seroquel, AstraZeneca was also required to enter into a Corporate Integrity Agreement (the "CIA") with the Office of Inspector General of the Department of Health and Human Services ("HHS").

42. Under the terms of the CIA, AstraZeneca was required to meet certain compliance regulations for five (5) years.

43. Defendant Astra Tech AB ("Astra Tech") is a foreign corporation having its principal place of business at 590 Lincoln Street, Waltham, Massachusetts. Astra Tech was originally based in Moelndal, Sweden.

44. Upon information and belief, at the time of its purchase by DENTSPLY, Astra Tech was the world's third-largest dental implants maker.

45. At all relevant times, Defendants were employers and employed Relators and /or caused Relators' employer to take actions against Relators within the meaning of and in violation of Section 3730(h) of the False Claims Act. 31 U.S.C. §3730(h).

IV. REGULATORY FRAMEWORK

A. Federal and State Government Health Programs

46. The Federal and State governments, through their Medicaid and Medicare programs, are among the principal purchasers of Defendants' products.

47. Medicare is a federal government health program primarily benefitting the elderly created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare began paying for over-the-counter drugs or for most self-administered prescription drugs after the

Medicare Prescription Drug Improvement and Modernization Act of 2003 was fully implemented.

48. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the Federal government and those State governments participating in the program. The Federal government also separately matches certain State expenses incurred in administering the Medicaid program. While specific State Medicaid coverage guidelines vary, Medicaid's coverage and reimbursement requirements are generally modeled after Medicare's coverage.

49. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program.

50. TRICARE is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

51. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for about 8 million Federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan.

52. FEHBP plans are managed by the Office of Personnel Management.

B. The False Claims Act

53. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendment s enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. The FCA was again strengthened by additional amendments in 2009 and 2010. The 2009 amendments expanded defendant liability, strengthened retaliation protections, and made it easier for federal, state, and local governments to prosecute FCA actions. The 2010 amendments clarified the definition of who is an "original source" of a FCA disclosure.

54. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2), (7). The FCA empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

55. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to prescribe a reimbursable drug, and promoting off-label uses of such drugs by a person who seeks reimbursement from a Federal Government health program for the drug, or who causes an other to do so, while certifying compliance (or while causing another to so certify) with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute, and the Food, Drug and Cosmetics Act, or billing the Government as if in compliance with these laws, violates the FCA.

C. FDA Regulation of Drug Marketing and Advertising

56. The FDA regulates drugs based on the "intended uses" for such products. A manufacturer that wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

57. The Food and Drug Act requires that all "new drugs," 21 U.S.C. § 321(p), be approved by the FDA as safe and effective prior to marketing. The marketing of a new drug without pre-approval from the FDA violates 21 U.S.C. §§ 355 and 331(d), of the Food, Drug and Cosmetics Act ("FDCA").

58. The FDA reviews a pharmaceutical manufacturer's application for approval of a new drug to determine whether the drug's intended use is safe and effective. 21 U.S.C. § 355. "Off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA scrutiny and approval, i.e., for purposes not approved by the FDA.

59. Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). A "medically accepted indication" includes only those indications approved by the FDA and certain "off-label" uses that are "supported by one or more citations included, or approved for

inclusion, in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6). Many States further restrict drugs by use of formularies or prior approval processes that aim to restrict off-label uses.

60. Once a drug is approved for a particular use, the FDA allows doctors to prescribe the drug for medical uses that are different from those approved by the FDA. The FDA also allows doctors to request information from drug manufacturers about off-label uses of FDA-approved drugs. However, with very few exceptions, the FDA prohibits drug manufacturers from marketing, advertising, or promoting a drug for a use that the FDA has not approved.

61. Pursuant to the FDCA, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates, among other things, the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies in promoting and selling FDA-approved prescription drugs. In particular, sales representatives who engage in personal interactions with providers may not promote drugs for use outside the FDA approved label and indications.

62. Any failure by a pharmaceutical company to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. 21 U.S.C. §§ 331(a)-(b), 352(a), (f), (n).

63. Any presentations, promotions, or marketing to physicians of products for use in a manner other than that approved for labeling purposes by the FDA is considered off-label marketing and is proscribed by the FDA. 21 U.S.C. §§ 331(a)-(b), 352(a), (f).

64. FDA regulations, summarized in Defendants' corporate compliance codes, prohibit pharmaceutical companies from actively discussing or detailing off-label uses of drugs in a promotional manner and/or misrepresenting product efficacy and safety. If a physician makes an

unsolicited request for information about an off-label use of a drug, a sales representative may not respond except to request information from Defendants' Medical and Drug Information Desk and/or delivering to the physician's office any articles or studies that address the physician's inquiry and are approved by Defendants' pharmaceutical Product Review Committee and filed with the FDA. FDA regulations, however, prohibit representatives from discussing or detailing studies of off-label uses under any circumstance.

65. Verbal use of Defendants' Medical Drug Information is a prohibited practice because the FDCA requires that the off-label promotion only be disseminated to doctors in writing, that the written materials meet applicable scientific criteria, and that the materials be properly disclosed in advance to the FDA.

66. False marketing and advertising claims of pharmaceutical efficacy and false claims of comparative superiority are prohibited under the FDCA. 21 C.F.R. § 202.1(e)(6)(ii).

67. The FDA prohibits manufacturers from making claims in drug marketing materials that the FDA previously rejected and were not included in the package insert. Thus, a marketing scheme utilizing such claims is prohibited by FDA marketing and advertising statutes and regulations. 21 C.F.R. § 202.1.

68. The United States and the States would not have issued reimbursements for off-label sales had they known the truth about Defendants' illegal marketing scheme. Every reimbursement sought from Medicaid, Medicare, and other government health care programs for such purchases as a result of Defendants' aggressive and illegal off-label marketing constitutes a false claim under the FCA.

D. Regulation of Medical Devices

69. The FDA also regulates the manufacturing, distribution and marketing of medical devices.

70. Under the FDCA, the term "device" includes "an instrument, apparatus, implement, machine, contrivance, implant, in vivo reagent, or other similar or related article, including any component, part, or accessory, which is … intended for use in the … cure, mitigation, [or]treatment … of disease, in man … or intended to affect the structure or any function of the body of man … which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

71. All devices marketed in interstate commerce in the United States are assigned to one of three regulatory classes, Class I, Class II or Class III, according to the degree of regulatory control necessary to assure the safety and efficacy of the device.

72. Pursuant to the FDCA, every manufacturer of a new device is required to obtain clearance or approval from the FDA prior to marketing its device.

73. A manufacturer may submit a premarket notification to obtain FDA clearance. A premarket notification is also known as a 510(k), named for the relevant provision of the FDCA, 21 U.S.C. § 360(k). To obtain clearance pursuant to a 510(k), the FDA must make a finding that the device is "substantially equivalent" to a "predicate" device, *i.e.*, a device that has been classified into Class I or Class II, or any device that is covered by a "cleared" 510(k). *See* 21 U.S.C. § 360c(f)(1).

74. "Substantially equivalent" means that the new device has the same intended use and the same technological characteristics as the predicate device, or it has the same intended use and

different technological characteristics, but the information submitted in the 510(k)demonstrates that the new device is as safe and effective as the predicate and does not raise different questions regarding safety and effectiveness than the predicate. *See* 21 U.S.C. § 360c(i)(1)(A); *see also* 21 C.F.R. § 807.100(b).

75. Clearance through the 510(k) process does not constitute FDA "approval" of the device; it limits the cleared use of the device to those indications listed in the application as the intended uses. 21 U.S.C. §352(f); 21 C.F.R. § 801.5; 21 C.F.R. §807.97.

76. The manufacturer of a medical device is not permitted to promote its device for any use other than the intended use as stated on the label as cleared or approved by the FDA.

77. Promotion of a medical device for a use other than its intended use as stated on the label renders the device "misbranded" under the FDCA. 21 U.S.C. § 331(a)-(b); *id.* § 352(a), (f), (q).

78. Promotion of a device for any indication not approved or cleared by the FDA and indicated on the label is considered "off-label" promotion and is unlawful. *See* 21 U.S.C. §331(d).

79. The FDCA prohibits introducing a medical device that is adulterated or misbranded into interstate commerce. *See* FDCA § 301(a), 21 U.S.C. § 331(a).

E. The Medicare Fraud & Abuse/Anti-Kickback Statute

80. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by a fine of up to $25,000 and imprisonment for up to 5 years.

81. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders or from receiving remuneration that takes into account the volume or value of any referrals or business generated. 42 C.F.R. § 1001.952(f). Remuneration paid to providers is an illegal kickback when it is paid to induce or reward the use of medical devices by dental healthcare professionals. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary use of certain devices and products, and excessive reimbursements. Such kickbacks also reduce a patient's healthcare choices as unscrupulous or unknowing physicians steer their patients to various drug products based on the physician's own financial interests rather than the patient's medical needs. follow

82. The Medicare Anti-Kickback Statute provides eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statute. 42 U.S.C. § 1320a-7(b)(3). None of the available statutory exceptions or regulatory safe harbors protect Defendants' conduct in this case.

83. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of any individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Act to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. 42 U.S.C. § 1320a-7a(a)(7).

84. As detailed below, Defendants' marketing repeatedly violated provisions of the Anti-Kickback Statute and the FCA because Defendants' improper kickbacks and incentives induced dental healthcare professionals to use Defendants' devices and products when they otherwise would not have and many of those devices and products were paid for by Medicare, Medicaid, TRICARE/CHAMPUS and other government-funded health insurance programs.

85. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a per se prohibition against kickbacks.

86. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under Medicare, Medicaid, and/or TRICARE/CHAMPUS programs.

F. Stark Law - The Medicare/Medicaid Self-Referral Statute

87. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn *et seq.*, known as the "Stark" law, prohibits a medical device manufacturer from paying remuneration to healthcare professionals for referring Medicare and Medicaid patients to the manufacturer for certain "designated health services," where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). *See also* 42 U.S.C. § 1395nn(a)(1), (g)(1).

88. Defendants' marketing of their products and devices repeatedly violated the provisions of the Stark Law and the FCA because Defendants' unlawful payments, services, and

excessive samples provided to dental healthcare professionals induced those dental healthcare professionals to use or prescribe Defendants' products when they otherwise would not have, and many of those devices were paid for by Medicare, Medicaid and other Government-funded health insurance programs.

G. The Medicaid Rebate Statute

89. The Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, is designed to return money to the Medicaid program in the form of rebates from drug manufacturers. Federal law provides that drug manufacturers must pay rebates to the states to ensure that the Medicaid program is paying the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser in the United States, inclusive of cash discounts, free goods, kickbacks, volume discounts, and rebates. The "best price" provision is intended to ensure that the Government is being provided the lowest price on drugs.

90. To have their drugs eligible for Medicaid payment, all drug manufacturers must provide "best price" information to the Centers for Medicare and Medicaid Services ("CMS"). CMS uses this "best price" information to calculate rebates payable to the Medicaid program.

91. Drug manufacturers provide both "best price" information and Average Manufacturer Price information to CMS. CMS then calculates a unit rebate amount and provides that information to State Medicaid agencies. The States then consider utilization data provided by pharmacies, and the unit rebate amount, to calculate the rebate owed to them by the manufacturer. The entire system, however, relies upon manufacturers honestly conveying to CMS correct "best price" information and Average Manufacturer Price information. Any overstatement of the best price, whether intentional or unintentional, will cause an underpayment in rebate amounts.

92. The Medicaid Rebate Statute states, in part, that the term "best price" shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). 42 U.S.C. § 1396r-8(c)(1)(c)(ii).

93. The Federal Government has great financial interest in the program. The Medicaid Rebate Statute provides that amounts received by the *Qui Tam* States under the "best prices program" shall be considered to be a reduction in the amount expended under the State Medicaid Plan for purposes of calculating the federal contribution to State Medicaid programs. 42 U.S.C. § 1396r-8(b)(1)(B).

94. As a result of pervasive "best price" fraud, the Office of the Inspector General of the United States Department of Health and Human Services promulgated compliance materials on May 5, 2003, which observed that manufacturers have "a strong financial incentive to hide de facto pricing concessions" (in particular, kickbacks and price discounts) that could affect "best price" calculations and trigger increased Medicaid rebates. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FEDERAL REGISTER 23731, 23735 (May 5, 2003). The Office of the Inspector General instructed manufacturers to report "best prices" which "accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." *Id.* at 23733-23734. According to the Office of the Inspector General, "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes." *Id.*

95. Defendants' conduct repeatedly violated the provisions of the Medicaid Rebate Statute.

V. DEFENDANTS' MARKETING SCHEMES PROHIBITED BY THE FALSE CLAIMS ACT

96. As summarized above and set forth in detail below, Defendants caused the submission of false claims by engaging in two distinct courses of conduct in violation of the FCA and FDCA.

97. Relators are aware of numerous allegations of fraudulent conduct by Defendants, including, but not limited to, kickbacks, best price violations, and off-label marketing.

98. The evidence Realtors have included call notes, emails, sales data, promotional items, and return on investment information.

99. This evidence will demonstrate the following violations of federal and state statutes:

a) cash payments, free products and discounts, and gifts to dental healthcare professionals for referrals to dental surgeons who use DENTSPLY products;

b) significant discounts to distributors and direct purchasers in return for promotion of their product and access to their network of providers;

c) outlandish gifts and promotional items including trips to Germany, tickets to shows, concerts and sporting events, gifts for providers and family members in exchange to the promotion and use of DENTSPLY products;

d) DENTSPLY exaggerated its reported product "best prices" to state and federal government programs, which are used to determine government reimbursement for procedures, then sold the products to physicians at sharply reduced prices

e) off-label marketing of various products for unapproved uses; and

f) false promotion to hide significant safety concerns and inflate efficacy.

100. Relators also have evidence of serious safety concerns about some DENTSPLY products. Some of the products sold by DENTSPLY such as files (used for implant and root canal work) are supposed to be used once and discarded in order to prevent infection and disease. However, DENTSPLY and Astra Tech sales representatives not only knew of providers who use these products multiple times rather than disposing of them, but encouraged dental healthcare professionals to engage in this practice as a way to increase their profits. Doing so allowed the providers to bill and get reimbursed for the same item used on numerous patients while exposing the patients increased infection and disease.

101. A high-ranking member of DENTSPLY's management, Brian Bashaw (Director of Sales, Clinical Area East) stated, in response to a question about marketing practices during a managers' conference call in or around late 2012, that DENTSPLY was "hoping we will continue to go unnoticed."

102. Relators possess direct and independent knowledge of the various schemes, misconduct and illegal practices of Defendants, including, but not limited to:

1. DENTSPLY's management directed and instructed DENTSPLY's sales representatives to make unsubstantiated efficacy claims about DENTSPLY products, including implants, to dental healthcare professionals and consumers;
2. DENTSPLY's management placed pressure on DENTSPLY's sales representatives to implement and use illegal and improper sales strategies, including touting the Vortex file system as a "one file system" though the system actually requires multiple files to operate, in order to market and sell DENTSPLY's products;
3. DENTSPLY's management failed to clearly identify FDA indications for DENTSPLY's sales representatives;

4. DENTSPLY's management directed and instructed DENTSPLY's sales representatives to make unsubstantiated safety claims about DENTSPLY products, including implants, to dental healthcare professionals and consumers;
5. DENTSPLY's management directed and instructed DENTSPLY's sales representatives to make false and misleading safety claims about DENTSPLY products, including implants, to dental healthcare professionals and consumers through marketing plans, Advisory Boards, promotional materials, and publication activities.

103. DENTSPLY's management placed pressure on DENTSPLY's sales representatives to make sales, including often telling DENTSPLY's sales representatives to "Get the sale by any means necessary" and continually threatening the job security of DENTSPLY's sales representatives if such instructions were not followed.

104. For example, DENTSPLY's management was aware of, and directed and instructed DENTSPLY's sales representatives to ignore, the fact that numerous dentists and orthodontists would make multiple use of files that were only supposed to be used on one occasion. DENTSPLY management turned a "blind eye" to healthcare providers reusing files so as not to lose sales. Nor did DENTSPLY report the inappropriate use of the equipment to the FDA, or any other government entity.

105. Multiple use of files can lead to root canal failure and major medical issues, resulting in tooth and surrounding bone loss.

106. Similarly, the off-label promotion of 3cc vials of Mineralized and Demineralized Cortical Powder when the smaller .25, .5, and 1 cc vials were on back order encouraged "vial

splitting", which created a safety risk. In fact, DENTSPLY management knew that such promotion would create such a risk

107. DENTSPLY's sales representatives, as well as DENTSPLY marketing employees, used studies and articles as the basis for promotional messages about unapproved uses of DENTSPLY products, including implants. For example, DENTSPLY's sales representatives were instructed to make copies of studies discussing off-label uses for DENTSPLY products, including implants, available to patients and dental healthcare professionals.

108. DENTSPLY marketing materials, including the brochure "One System For All Your Implant Needs", claims "predictable results for all patients, in all indications, including compromised cases, where implants with other surface treatments may be less effective." DENTSPLY has no FDA approval to make this claim.

109. DENTSPLY's management has not created or implemented a policy or procedure for DENTSPLY sales representatives to address questions of an off-label nature with respect to certain DENTSPLY products

110. DENTSPLY has a large number of speakers who receive product discounts for being speakers; however, even though the speakers do not have any speaking engagements that are scheduled and/or implemented every year, they still receive the discount. DENTSPLY considers this a method to provide a kickback to a customer.

111. DENTSPLY does not state the indication for various products on any marketing literature for any of its products. For example, for the ANKYLOS® Implant system, DENTSPLY states that "all indications in one system", but the marketing literature does not list the indications and that claim is false.

112. DENTSPLY routinely and knowingly participated in HIPAA/patient privacy violations.

113. DENTSPLY speakers regularly provided customer information, photographs and case information without patient approval.

114. DENTSPLY sales representatives and management repeatedly share and circulate information from patient cases as examples to be used in the field. This information is provided by doctors to DENTSPLY without the patient's consent, which DENTSPLY knows and ignores.

115. DENTSPLY management expects sales representatives to handle patient issues and cases directly. DENTSPLY management requires sales representatives to assist on cases and recommend certain DENTSPLY products to the dentists and orthodontists.

116. DENTSPLY, particularly in its Implants division, paid illegal remuneration such as stocking allowances and consignment agreements based on volume, that caused the submission of false and fraudulent claims to the federal health care programs.

117. DENTSPLY, particularly in its Implants division, paid illegal remuneration such as price protection payments, market share payments, and free goods in order to induce clinicians, labs and GPOs to buy its products, thus causing the submission of false and fraudulent claims to the federal health care programs.

118. DENTSPLY, particularly in its Implants division, used and conspired to use various forms of financial arrangements and inducements to induce specialists to cause providers to use DENTSPLY products and increase DENTSPLY's market share. These arrangements caused hospitals and physicians to submit false and fraudulent claims for various surgical procedures using DENTSPLY products.

119. Finally, DENTSPLY exaggerated its reported product "best prices" to state and federal government programs, which are used to determine government reimbursement for procedures, then sold the products to physicians at sharply reduced prices, enabling them to collect excess reimbursement from private and government insurers thereby marketed the spread and concealed "best price." This practice also defrauded consumers of the appropriate coverage of their implant, grafting, and endodontic procedures.

120. Many, if not all, of the fraudulent actions and deceitful conduct described above was also performed by Astra Tech sales representatives under the supervision and knowledge of Astra Tech and AZ management.

121. Similarly, Astra Tech makes the following claims, and has made these claims in the past:

1. That its BioManagement Complex implant system is a unique combination of four key features. However, it is not a "unique" system, as other implant systems also have these features;
2. That its "micro thread at the implant neck provides bio mechanical bone stimulation" when there is no clinical evidence to support this no FDA approval to make this claim;
3. That there are "predictable results for all patients, in all indications, including compromised cases, where implants with other surface treatments may be less effective" when there is no FDA approval to make this claim; and
4. In marketing the Astra 3.0 implant, Astra Tech claims that this implant can be used everywhere, when, in reality, because of the narrow width of the this implant it has restrictions that Astra Tech never mentions

122. Moreover, after DENTSPLY acquired Astra Tech, DENTSPLY promoted the Astra Tech Implant line for various off-label uses.

COUNT I
False Claims Act - Presentation of False Claims
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A), as amended in 2009

123. The allegations of the preceding paragraphs are realleged as if fully set forth below.

124. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information which supported claims to CMS, and Federal Programs, with actual knowledge of the falsity of the information that supported these claims, cause, and continues to be causing, the use of false or fraudulent materials or information to support claims paid by the government.

125. Through the acts described above and otherwise, Defendants and their agents and employees knowingly presented or caused to be presented to the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

126. The United States of America, unaware of the falsity of the claims and statements made by Defendants, and in reliance on the accuracy of these claims and statements, paid and is continuing to pay or reimburse claims for Defendants' products and devices for patients enrolled in federally-funded medical care programs.

127. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT II
False Claims Act - Making or Using False Records or Statements to Cause Claim to be Paid
31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), as amended in 2009

128. The allegations of the preceding paragraphs are realleged as if fully set forth below.

129. Through the acts described above and otherwise, Defendants and their agents and employees knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2), and, as amended, 31 U.S.C. § 3729(a)(1)(B), in order to get false or fraudulent claims paid and approved by the United States Government.

130. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and is continuing to pay or reimburse claims for Defendants' products and devices for patients enrolled in federally-funded medical care programs.

131. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT III
False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C) as amended in 2009

132. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

133. Through the acts described above and otherwise, Defendants entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended 31 U.S.C. § 3729(a)(1)(C). Defendants also conspired to omit disclosing or to actively conceal facts which, if known, would have reduced Government obligations to it or resulted in repayments from it to Government programs.

134. Defendants, their agents, and their employees have taken substantial steps in furtherance of those conspiracies, *inter alia*, by preparing false records, by submitting claims for

reimbursement to the Government for payment or approval, and by directing their agents and personnel not to disclose and/or to conceal its fraudulent practices.

135. The United States, unaware of Defendants' conspiracy or the falsity of the records, statements and claims made by Defendants, their agents and employees, and as a result thereof, has paid and continues to pay millions of dollars that it would not otherwise have paid. Furthermore, because of the false records, statements, claims, and omissions by Defendants and their agents and employees, the United States has not recovered federal funds from Defendants that otherwise would have been recovered.

COUNT IV
False Claims Act - Making or Using False Records or Statements to Conceal, Avoid and Decrease Obligation to Repay Money
31 U.S.C. § 3729(a)(7), 31 U.S.C. § 3729(a)(1)(G), as amended in 2009

136. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

137. Through the acts described above and otherwise, in violation of 31 U.S.C. § 3729(a)(7), and, as amended, 31 U.S.C. § 3729(a)(1)(G), Defendants and their agents and employees knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, and decrease Defendants' obligation to repay money to the United States Government that Defendants improperly or fraudulently received. Defendants also failed to disclose material facts that would have resulted in substantial repayments to the United States Government.

138. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

139. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false or

fraudulent records or statements, to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States of America and the *Qui Tam* States in violation of 31 U.S.C. §3729(a)(7).

140. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America, and the *Qui Tam* States, have been, and may continue to be, severely damaged.

COUNT V
California False Claims Act
Cal. Gov't Code § 12651 *et seq.*

141. The allegations of the preceding paragraphs are realleged as if fully set forth below.

142. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq.*

143. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

144. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

145. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VI
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-304 *et seq.*

146. The allegations of the preceding paragraphs are realleged as if fully set forth below.

147. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act. Colo. Rev. Stat. § 25.5-4-304 *et seq.*

148. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Colorado Medicaid Program false or fraudulent claims for the improper payment or approval of Defendants' products and used false or fraudulent records to accomplish this purpose.

149. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

150. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VII
Connecticut False Claims Act
Conn. Gen. Stat. § 17b-301a *et seq.*

151. The allegations of the preceding paragraphs are realleged as if fully set forth below.

152. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301 *et seq.*

153. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the state and the Connecticut Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

154. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

155. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VIII
Delaware False Claims Act
Del. Code Ann. tit. 6, § 1201 *et seq.*

156. The allegations of the preceding paragraphs are realleged as if fully set forth below.

157. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 *et seq.*

158. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of Defendants' products for its pharmaceuticals mentioned above and used false or fraudulent records to accomplish this purpose.

159. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

160. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT IX
Florida False Claims Act
Fla. Stat. Ann. § 68.081 *et seq.*

161. The allegations of the preceding paragraphs are realleged as if fully set forth below.

162. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081 *et seq.*

163. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims for the improper payment or approval of Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

164. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

165. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT X
Georgia False Medicaid Claims Act
Ga. Code Ann. § 49-4-168 *et seq.*

166. The allegations of the preceding paragraphs are realleged as if fully set forth below.

167. This is a claim for treble damages and civil penalties under the False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

168. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

169. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

170. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XI
Hawaii False Claims Act
Haw. Rev. Stat. § 661-22 *et seq.*

171. The allegations of the preceding paragraphs are realleged as if fully set forth below.

172. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22 *et seq.*

173. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

174. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

175. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XII
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/1 *et seq.*

176. The allegations of the preceding paragraphs are realleged as if fully set forth below.

177. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 Ill. Comp. Stat. 175/1 *et seq.*

178. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

179. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

180. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIII
Indiana False Claims and Whistleblower Protection
Burns Ind. Code Ann. § 5-11-5.5-1 *et seq.*

181. The allegations of the preceding paragraphs are realleged as if fully set forth below.

182. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Law. Burns Ind. Code Ann. § 5-11-5.5-1 *et seq*.

183. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

184. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

185. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIV
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. § 46:437.1 *et seq.*

186. The allegations of the preceding paragraphs are realleged as if fully set forth below.

187. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1 *et seq*.

188. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and knowingly used false or fraudulent records to accomplish this purpose.

189. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

190. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XV
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. §2-601 *et seq.*

191. The allegations of the preceding paragraphs are realleged as if fully set forth below.

192. This is a claim for treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann., Health-Gen. §2-601 *et seq*.

193. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Maryland Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

194. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

195. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVI
Massachusetts False Claims Act
Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

196. The allegations of the preceding paragraphs are realleged as if fully set forth below.

197. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

198. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

199. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

200. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVII
Michigan Medicaid False Claim Act
Mich. Comp. Laws §400.601 *et seq.*

201. The allegations of the preceding paragraphs are realleged as if fully set forth below.

202. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act. MCL § 400.601 *et seq*.

203. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Michigan Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

204. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

205. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVIII
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq.*

206. The allegations of the preceding paragraphs are realleged as if fully set forth below.

207. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act. Minn. Stat. § 15C.01 *et seq.*

208. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

209. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

210. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIX
Montana False Claims Act
Mont. Code Ann. §17-8-401 *et seq.*

211. The allegations of the preceding paragraphs are realleged as if fully set forth below.

212. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Ann. § 17-8-401 *et seq*.

213. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Montana Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

214. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

215. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XX
Nevada False Claims Act
Nev. Rev. Stat. § 357.010 *et seq.*

216. The allegations of the preceding paragraphs are realleged as if fully set forth below.

217. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. § 357.010 *et seq.*

218. The allegations of the preceding paragraphs are realleged as if fully set forth below. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

219. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

220. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXI
New Hampshire Medicaid Fraud and False Claims Law
N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

221. The allegations of the preceding paragraphs are realleged as if fully set forth below.

222. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law. N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

223. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

224. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

225. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXII
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1 *et seq.*

226. The allegations of the preceding paragraphs are realleged as if fully set forth below. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act. N.J. Stat. § 2A:32C-1 *et seq.*

227. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for the improper payment or approval for off-label and improper uses of Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

228. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

229. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-1 *et seq.*

230. The allegations of the preceding paragraphs are realleged as if fully set forth below.

231. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1 *et seq.*

232. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

233. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

234. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIV
New York False Claims Act
N.Y. State Fin. Law § 187 *et seq.*

235. The allegations of the preceding paragraphs are realleged as if fully set forth below.

236. This is a claim for treble damages and civil penalties under the New York False Claims Act. N.Y State Fin. Law § 187 *et seq.*

237. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records material to a false or fraudulent claim to accomplish this purpose.

238. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

239. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXV
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 *et seq.*

240. The allegations of the preceding paragraphs are realleged as if fully set forth below.

241. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Stat. § 1-605 *et seq.*

242. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

243. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

244. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVI
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 § 5053 *et seq.*

245. The allegations of the preceding paragraphs are realleged as if fully set below.

246. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053 *et seq.*

247. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

248. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

249. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVII
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

250. The allegations of the preceding paragraphs are realleged as if fully set forth below.

251. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq.*

252. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

253. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

254. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVIII
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

255. The allegations of the preceding paragraphs are realleged as if fully set forth below.

256. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181 *et seq.*

257. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Tennessee Medicaid Program (i.e. TennCare) false or fraudulent claims for the improper payment or approval of the Defendants' products and devices described above and used false or fraudulent records to accomplish this purpose.

258. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

259. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIX
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

260. The allegations of the preceding paragraphs are realleged as if fully set forth below.

261. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

262. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly made a claim to the Texas Medicaid Program for a product that has been adulterated, debased, or mislabeled, or that is otherwise inappropriate, and caused to be presented to the Texas Medicaid Program false or fraudulent

claims for the improper payment or approval of Defendants' products and used false or fraudulent records to accomplish this purpose.

263. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

264. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.1 *et seq.*

265. The allegations of the preceding paragraphs are realleged as if fully set forth below.

266. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-216.1 *et seq.*

267. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

268. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

269. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXI
Wisconsin False Claims Act
Wis. Stat. § 20.931 *et seq.*

270. The allegations of the preceding paragraphs are realleged as if fully set forth below.

271. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act. Wis. Stat. § 20.931 *et seq*.

272. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

273. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

274. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXII
District of Columbia False Claims Act
D.C. Code § 2-308.14 *et seq.*

275. The allegations of the preceding paragraphs are realleged as if fully set forth below.

276. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03 *et seq*.

277. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper payment or approval for off-label and improper uses of Defendants' products and devices and used false or fraudulent records to accomplish this purpose, and conspired with each other to effectuate this plan.

278. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

279. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXIII
The City of Chicago False Claims Act
Chicago Municipal Code, § 1-22-010 *et seq.*

280. The allegations of the preceding paragraphs are realleged as if fully set forth below.

281. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act. Chicago Municipal Code § 1-22-010 *et seq.*

282. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Chicago Department of Public Health false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

283. The City of Chicago Department of Public Health, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

284. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXIV
New York City False Claims Act
New York City Adm. Code, § 7-801 *et seq.*

285. The allegations of the preceding paragraphs are realleged as if fully set forth below.

286. This is a claim for treble damages and civil penalties under the New York False Claims Act, New York Adm. Code, § 7-801.

287. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to New York City false or fraudulent claims for the improper payment or approval of the Defendants' products and devices and used false or fraudulent records to accomplish this purpose.

288. The New York City Health and Hospitals Corporation, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

289. By reason of these payments, the New York City Health and Hospitals Corporation has been damaged, and continues to be damaged in a significant amount.

PRAYER FOR RELIEF

WHEREFORE, Relators request that judgment be entered against Defendants, ordering that:

a. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;

b. Defendants pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions;

c. Relators be awarded the maximum "relators' share" allowed pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

d. Relators be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

e. Relators be awarded all litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law;

f. Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

g. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

h. The United States, the Individual States, and Relators recover such other relief as the Court deems just and proper; and

a. Grant Relators such relief as is appropriate under the provisions of 31 U.S.C. Section 3730(h) of the False Claims Act;

REQUEST FOR TRIAL BY JURY

Relators hereby demand a trial by jury.

Respectfully submitted,

SHELLER, P.C.

Dated: January 9, 2014

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